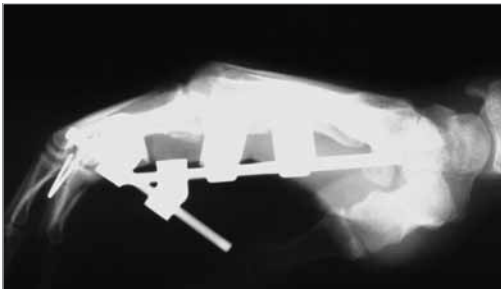




External Fixation System

External Fixation System

Since 1988, Acumed has been designing solutions for the demanding situations facing orthopaedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit and deliver quality products and instrumentation.



For many years, external fixation has been a well accepted technique to stabilize a variety of fractures. Acumed® is committed to providing unique and innovative fracture management solutions for the upper and lower extremities and has developed a dedicated line of external fixators suited especially for these areas. From our unique distal radius fracture system, to our innovative small bone fixation and distraction units, we have designed each system to provide ease of application, stability and precise fracture reduction.



The Stableloc External Fixator is a lightweight, radiolucent device designed to repair unstable distal radius fractures. The Stableloc allows the surgeon to gain initial reduction with the fixator in place and then independently adjust only those planes needing correction. For convenience, the device is packed sterile with everything needed to complete a case, including instrumentation and pins.

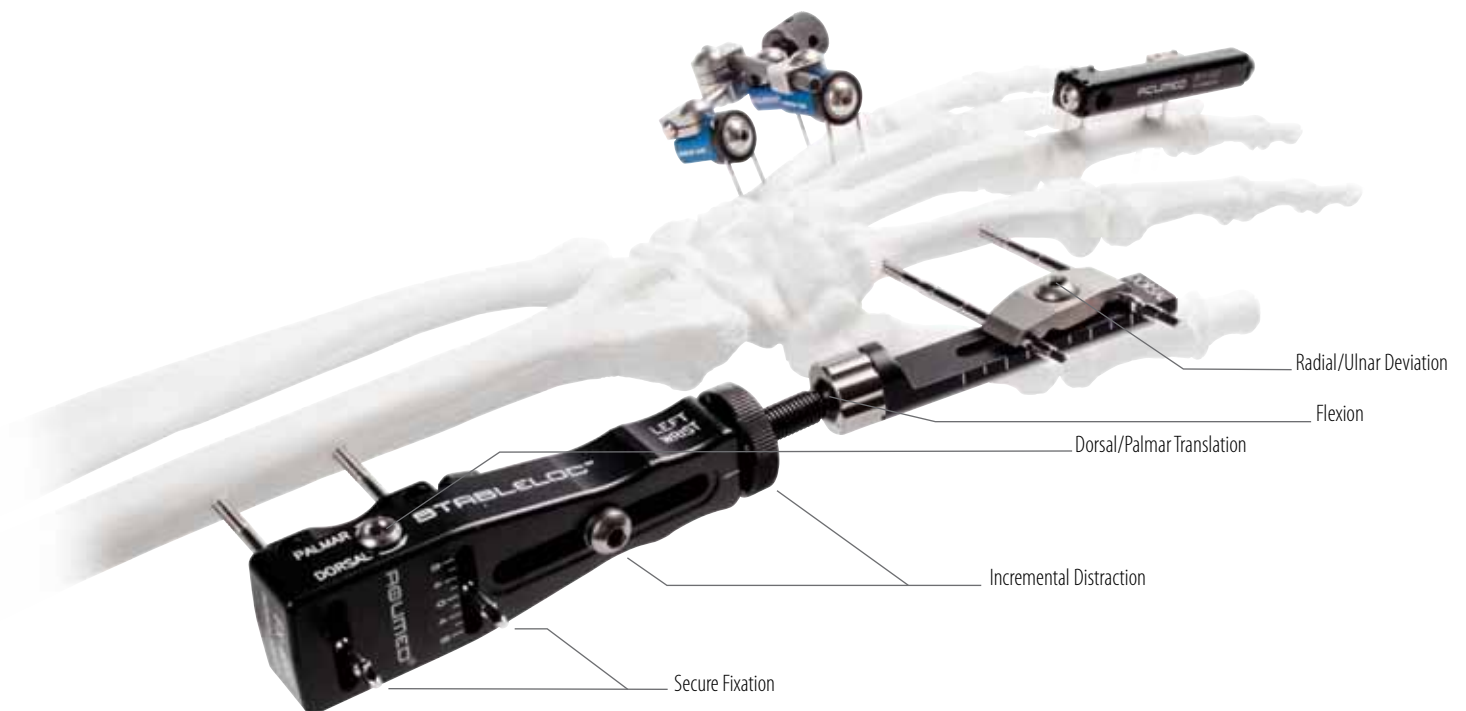
Versatility allows the surgeon to gain initial reduction with the fixator in place and then independently adjust only those planes needing correction. Adjustments may be made independently for distraction, radial/ulnar deviation, flexion/extension and dorsal/palmar translation.



The Sterile System is a complete and cost effective solution with simple instrumentation. The pins have a self-drilling option to reduce the number of surgical steps. Everything needed for the fixator application and adjustment is included in one compact kit.



Radiolucent Body aids in visualization for accurate fracture reduction. The Fixator is very lightweight for optimizing patient comfort.



Small Bone External Fixation System



Our Small Bone Fixator is an excellent solution for stabilizing various fractures including open and/or comminuted fractures, infected nonunions, fractures with length discrepancies as well as fusions and osteotomies. Typically the result of high-energy trauma, these injuries may require small external fixators that are simple to use, offer versatile pin placement options, are stable and cost effective. Acumed's Small Bone Fixator System is unique in satisfying all four of these requirements simultaneously.

The Small Bone Distractor is designed to aid with indications such as open or closed fractures, aseptic and infected nonunions, corrective osteotomies, length maintenance due to segmental bone loss and distraction lengthening of the metacarpals, metatarsals and phalanges.



Features of the Small Bone Distractor are the self-templating K-wire holes, allowing for percutaneous insertion of threaded K-wires from .045" to .062". These holes act as their own template, making for a straightforward procedure.

A Removable Handle on the Small Bone Distractor allows the surgeon to easily manipulate the device, while minimizing X-ray exposure.

Combining our Small Bone Fixator and Small Bone Distractor in one system, Acumed's Small Bone External Fixation System provides multiple innovative solutions for hand trauma, all in one tray.



Small Bone Fixation

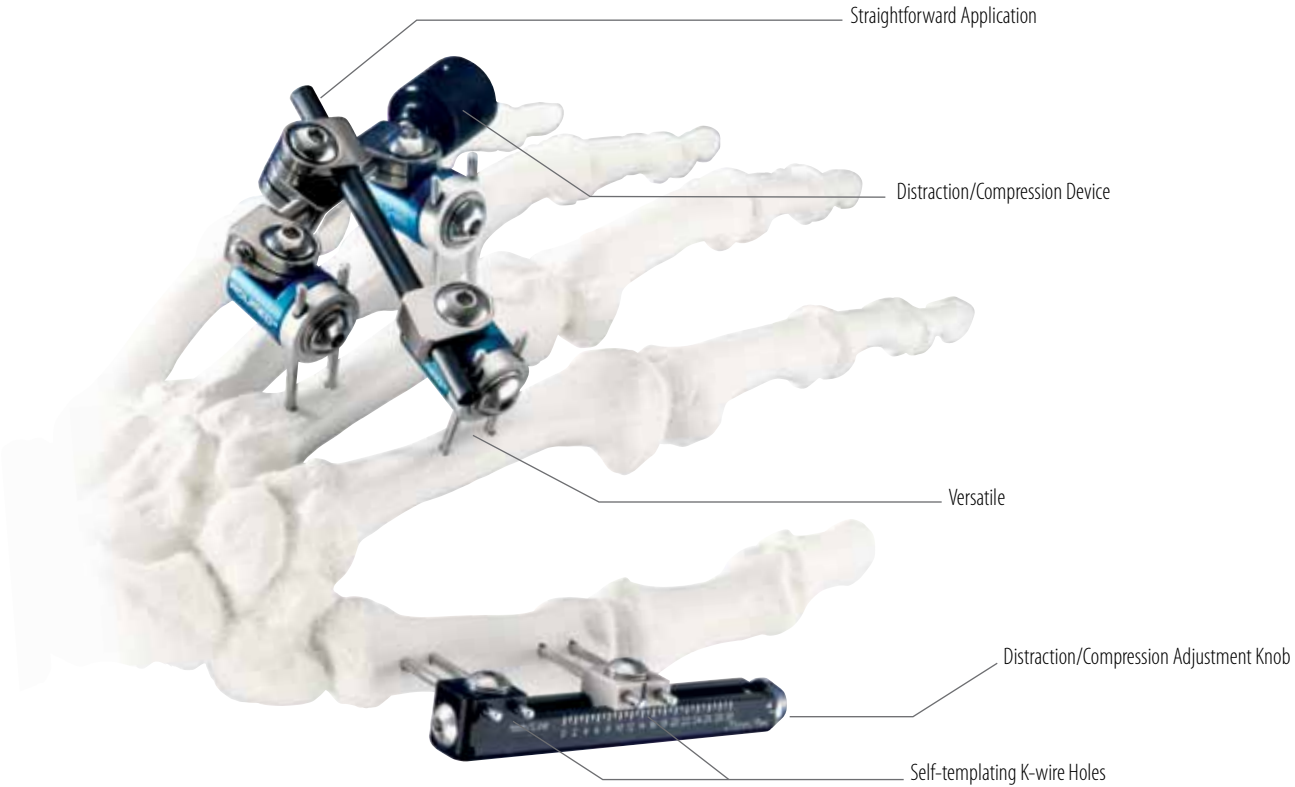
Straightforward Application of the Small Bone Fixator is achieved by clamping the blue housing assemblies on two or more sets of parallel K-wires and connecting the assemblies via carbon fiber or threaded stainless steel.

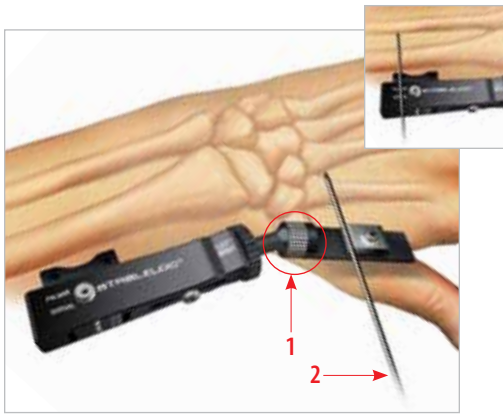


Versatile modular design enables pins to be located in multi-planar arrangements, allowing the frame to be built around the fractures.



Accurate Lengthening for corrective or fracture care, this lightweight, low-profile fixator accurately and easily adjusts to the appropriate distraction/compression desired by the surgeon.



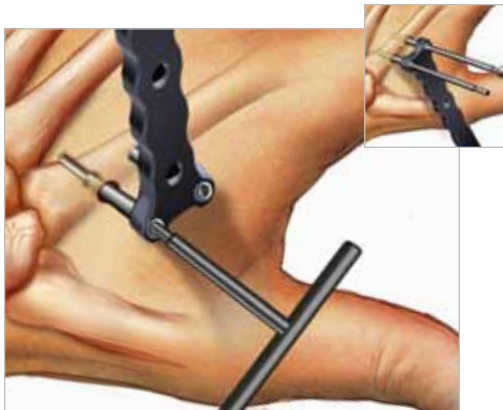


1 Pre-surgical Planning

Determine the proper position of the fixator in relation to the radius, the 2nd metacarpal and the center of wrist rotation. Align the fixator with the extended extremity, lining up the approximate center of wrist rotation with the ball joint (1). Locate and mark the position of the proximal and distal pins. The fixator should not be fully distracted or fully compressed when determining pin positions (2).

Placing the fixator in the transverse plane or rotated dorsally up to 20° will increase the accuracy of subsequent adjustments.

Note: This step insures that the fixator pins are placed within the working range of the fixator.

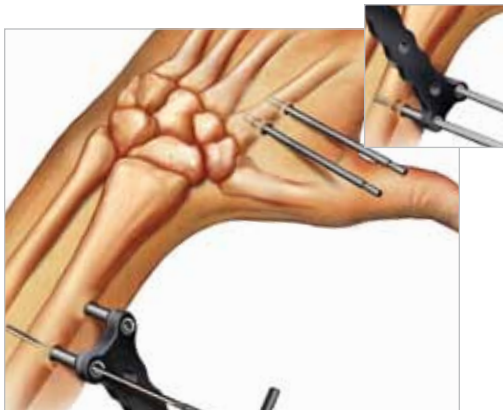


2 Insert Distal Pins:

The appropriate incision and dissection steps are carried out. Centering the longer cannula of the dual drill guide on the bone, the first pin is inserted with the T-handle pin driver through the base of the second metacarpal and can be extended into the first cortex of the third metacarpal, if desired. Although the pins have a self-drilling feature, a drill is provided if predrilling is needed due to dense bone.

Rotate the drill guide 180° so the short cannula is placed over the previously inserted pin. Making sure the longer cannula is centered on the bone, predrill and insert the second pin. Advance the pins until two to three threads have extended through the far cortex.

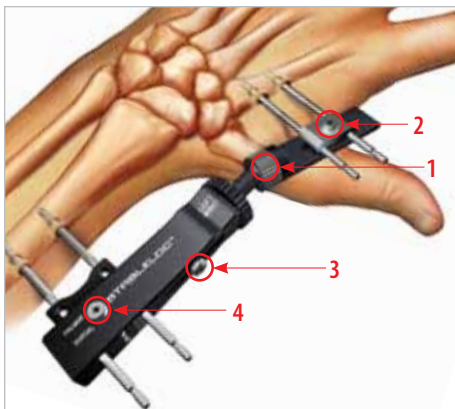
Note: The drill guide assures the pins are placed parallel.



3 Insert Proximal Pins:

After incision and careful dissection to the distal radius has been completed, the convex center of the radius is identified. Using the long cannula on the dual drill guide, drill bicortically through the radius and insert the first pin. The pins may also be used as self-drilling as described earlier. Remove the drill guide and rotate 180° placing the shorter cannula over the previously inserted pin. Insert the second pin in the same manner as the first radius pin.

Note: Use care when drilling through the radius to avoid over drilling.



4 Apply Stableloc Fixator:

Making sure the distal clamp is loose and the main body set screws are loose, slide the fixator onto the pins. Align the Stableloc on the wrist so the ball joint (1) is positioned over the center of wrist rotation. This will aid in the accuracy of subsequent adjustments.

Lightly tighten the distal pin clamp (2), the ball shaft locking screw (3), the ball joint set screw and the main body set screws (4) provisionally locking the fixator into position.

5 Distraction/Ligamentotaxis:

To apply distraction to aid fracture reduction, make sure the distraction nut (1) has advanced down the threaded ball shaft and is adjacent to the main body of the fixator. Loosen the ball shaft screw (2) with the provided T-handle hex driver. Turn the distraction nut towards the housing to apply the required amount of distraction. One complete revolution of the nut equals 1mm of distraction. Lock the ball shaft locking screw.

Note: The distraction nut is marked with "A,B,C,D" as a reference to indicate where distraction began.

**6 Dorsal/Palmar Translation:**

Place the hex wrench into the jack screw (1) on the dorsal side of the main body of the fixator. Turn the wrench *clockwise* for *palmar* translation and *counterclockwise* for *dorsal* translation. You are able to determine the amount of translation by the scale on the side of the Stableloc. There is 8mm of translation available in either direction.

**7 Radial/Ulnar Deviation:**

Gain proper anatomic alignment of the fracture on the radial/ulnar plane by loosening the distal pin clamp (1). This allows free movement in both the M/L and radial/ulnar direction.

Note: Traction can be lost when the distal pin clamp locking screw is loosened.

**8 Flexion/Extension:**

To achieve the desired angle of wrist flexion, first loosen the ball joint (1), adjust to the flexion desired, then lock the ball joint.

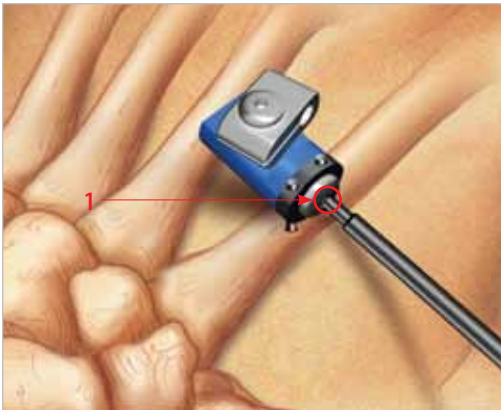
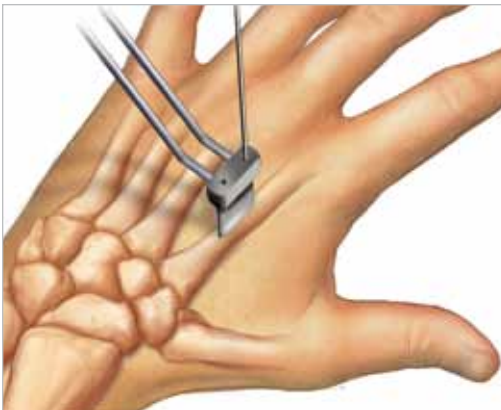
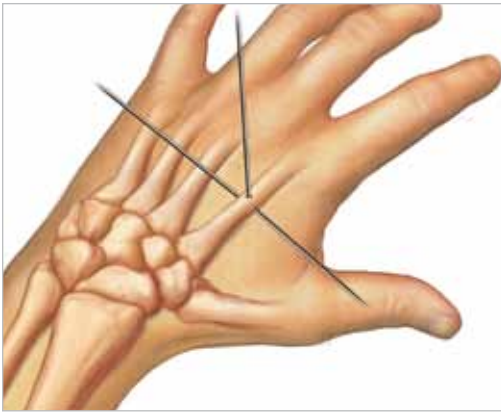
9 Post-op Protocol:

After completion of all adjustments, the fixator is locked into its final position. Wounds are dressed in routine sterile fashion and dry sterile gauze is wrapped around the pins to prevent pistoning of pins and soft tissue. The Stableloc Soc can then be applied to facilitate patient acceptance of the device.

Note: The surgeon will want to keep the hex driver for in-office adjustments, and the pin driver for pin removal at the appropriate time.



Small Bone Fixation



1 Pre-surgical Planning:

The versatility of the housing assemblies allows for the K-wire pairs to be placed in any plane between medial/dorsal/lateral. Both wire and rod clamps rotate to match wire placement.

2 K-wire Positioning:

Determine K-wire position by using the dual headed wire guide. .035" to .062" K-wires may be used for the Small Bone Fixation System.

3 Apply the Housing Assemblies:

Housing assemblies are secured to the wires by first inserting them through the holes in the wire clamp. Lightly tighten the clamp screw (1) to allow rotation of the blue assembly body. Repeat these steps as needed to add more Housing Assemblies.

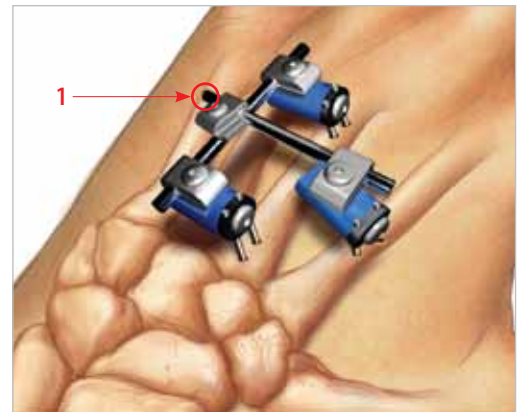
4 Create the Fixation Scaffold:

Housing assemblies are connected with either the provided carbon rods, or the threaded rods. Slide the selected rod through the loosened rod clamp (1).

Note: A threaded rod must be used in place of the carbon rods if the Distraction/Compression Device is to be used.

5 Secure Fixator:

Reduce the fracture and tighten all clamp screws and rod clamps to secure the fixator. Finally, cut all the K-wires to approximately 1cm or less from the housings. If a third housing assembly is required for stability, it may be attached to the first rod using the outrigger assembly (1).

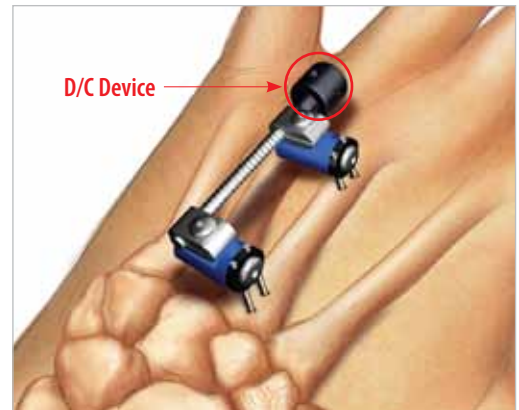


Distraction/Compression Options

Compression:

The distraction/compression device is threaded outside of the housing onto the threaded rod. Lightly loosen the rod clamp and tighten the D/C device toward the housing to compress the fracture. Tighten the rod clamp.

Note: Threaded rods must be used in conjunction with D/C device.



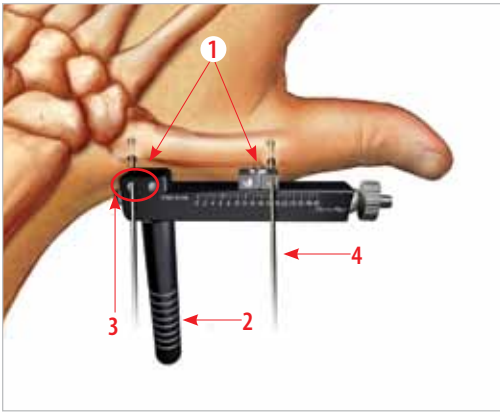
Distraction:

The D/C device wheel is threaded inside of the housing onto the threaded rod. Lightly loosen the rod clamp and tighten the D/C device toward the housing away from the fracture for distraction.

Note: Threaded rods must be used in conjunction with D/C device.



Small Bone Distractor



1 Insert First K-wires:

Loosen the clamp set screws (1). Using the handle (2) to hold the distractor in place, insert a single K-wire through the proximal clamp (3), perpendicular to the bone. Lightly tighten the proximal clamp set screws after the wire has advanced through the far cortex. Maintaining a parallel relationship between the distractor and the bone, insert a second K-wire through one of the holes in the distal clamp (4). Lightly tighten the distal clamp set screws after the wire has advanced through the far cortex.

Note: Cut K-wires to approximately 1cm or less from the distractor so they are out of the way for the subsequent K-wire insertion.



2 Insert Remaining K-wires:

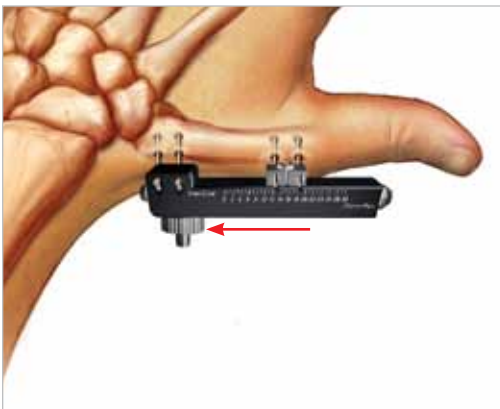
Loosen the proximal clamp set screws and insert the second K-wire until it advances through the far cortex. Tighten the clamp set screws and cut the wire to within 1cm or less of the distractor. Repeat this step for the second K-wire in the distal clamp.



3 Adjust Distraction Wheel:

Adjust the distraction wheel (1) accordingly to achieve the desired length. Each complete revolution of the distraction wheel will cause 0.75mm of travel for the distal wire clamp.

Note: Cut remaining K-wires to approximately 1cm or less from the distractor



4 Final Placement:

The distractor handle is discarded and replaced with the distraction wheel after distraction/compression has been completed. If needed, multiple distractors may be linked via the end clamp with 1.1mm to 1.6mm wire.

Stableloc

Complete Stableloc Kit	FX-4001-S
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Small Bone Fixator Set

Small Bone Fixator/Distractor Instrument Set	SBF-0000
Small Bone Housing Assembly (Set Contains 4)	SM-5100
Outrigger Assembly	SM-5200
60mm Carbon Fiber Rod	SMC-5060
60mm Threaded Rod	SMT-5060
90mm Carbon Fiber Rod	SMC-5090
90mm Threaded Rod	SMT-5090
Small Bone Fixator Knob	SM-5015
Pin Guide Assembly	SM-5080
3/32" Hex Key	HK-0024
Small Bone External Fixation Tray	SM-5061

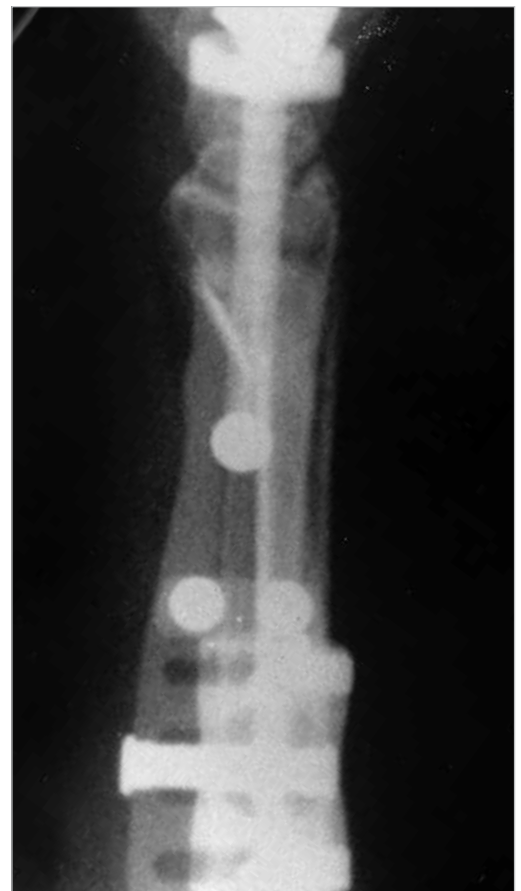
Small Bone Distractor

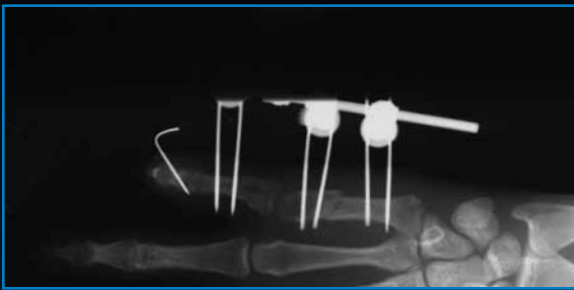
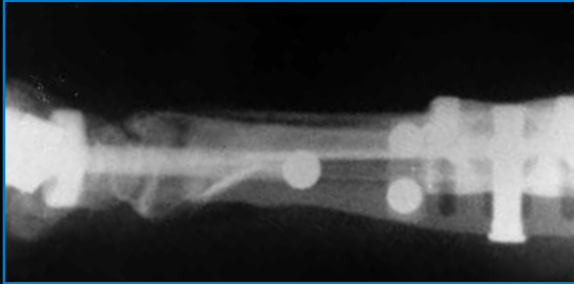
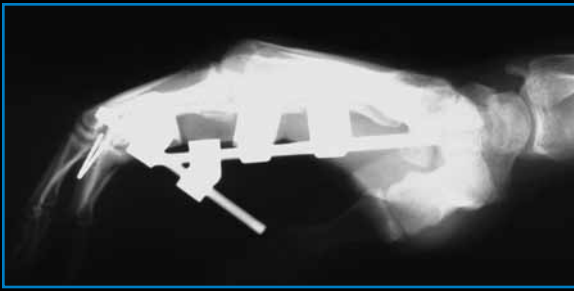
Small Bone Distractor with Handle	BD1-400
2.0mm Hex Wrench	AT-7004
1.5mm x 4" STT Guide Wire (not included with set)	WS-1504STT
2.4mm Bone Distractor Hex	BD1-410

The External Fixation System may also be used in combination with the following Acumed® Products:

- Acu-Loc®
- Acutrak®
- Acutrak 2®

For ordering information, please contact your local Acumed Sales Representative.





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Effective 04/2010

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